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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,574	11/12/2002	Dietmar Becher	07038-0004UI	6881

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,574

Applicant(s)

BECHER ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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DETAILED ACTION

Claims 1-22 are pending in the present application. This Office action is in response to the Amendment and Response filed 27 September 2004.

Response to Amendment

The rejection of claim 1 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendment.

The rejection of claims 2, 3, 8-11, 13, 14, 15, 16, 21 and 23 under 35 U.S.C. 102(b) as being anticipated by Siekstele et al. is withdrawn in view of Applicant's amendment.

The rejection of claims 2, 3, 8-16, 21 and 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn upon reconsideration of the rejection.

The rejection of claims 7 and 19 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment.

Claims 2, 3, 8-16, 21 and 22 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons already of record and those set forth below.

Any rejections or objections not repeated herein are withdrawn.

Response to Arguments

Claims 2, 3, 8-16, 21 and 22 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons already of record and

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those set forth below. Applicant's arguments filed 27 September 2004 have been fully considered but they are not persuasive.

Applicant argues that the written description rejection of the instant claims is improper because the claims now recite: a relevant portion of SEQ ID NO:1, nucleotides 1-1134, "or a part of" this sequence having promoter activity or SEQ ID NO:2 or a part of this sequence which has terminator activity. Applicant points to the specification on pages 10-11 and 13-15 for support of the claimed portions and points to the specification which discloses nucleotides 28-541 of SEQ ID NO:2 as having terminator activity. Moreover, Applicant argues that Applicant has "provided a functional limitation for the claimed subsequences."

First, the claims still recite portions or parts of either SEQ ID NO:1 or SEQ ID NO:2 not disclosed or exemplified in the specification. This is in spite of the amendment to limit SEQ ID NO:1 to nucleotides 1-1134 or a part of nucleotides 1-1134 of SEQ ID NO:1. Applicant still fails to teach the parts of nucleotides 1-1135, or parts of nucleotides 28-541 of SEQ ID NO:2 disclosed in the specification, which result in the claimed function. The portions of the specification referred to by Applicant disclose the specifically claimed plasmids and the expression of plasmids. No where do these pages teach the relevant identifying characteristics or parts of either nucleotides 1-1134 of SEQ ID NO:1 or SEQ ID NO:2 such that one of skill in the art would reasonably conclude that Applicant was in possession of the invention claimed. See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Applicant's argument that the functional limitation in the claims provide adequate description is noted however not persuasive. MPEP 2163(I)(A) is clear on this issue:

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A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function.” See *University of California v. Eli Lilly and co.* 119 F.3d 1559, 43 USPQ2d 1398 (1997). Applicant has not specifically defined any of the parts or portions of the sequences claimed that fall within the broad genus claimed. Applicant also fails to describe any structural characteristics commonly possessed by members of the genus such that one of skill in the art would recognize that Applicant was in possession of the full breadth of the invention claimed. Therefore, the functional limitation does not adequately describe the claimed genus.

Claims 4-7 and 17-20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. Courts have recognized the necessity and desirability of permitting an applicant for a patent to supplement the written disclosure in an application with a deposit of biological material which is essential to meet some requirement of the statute with respect to the

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claimed invention. Merck and Co., Inc. v. Chase Chemical Co., 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); In re Argoudelis, 434 F.2d 666, 168 USPQ 99 (CCPA 1970).

Applicant claims various plasmid constructs in the instant claims. In order to sufficiently enable the claimed plasmids, Applicant must make a biological deposit of each of them in addition to making assurances of availability. The deposit rules (37 CFR 1.801 - 1.809) set forth examining procedures and conditions of deposit which must be satisfied when a deposit is required. See MPEP 2402-2404.

Allowable Subject Matter

Claim 1 is allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER